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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/577,655	05/01/2006	Kazuhiko Machida	0425-1257PUS1	3246		
2252	7590	08/21/2009				
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				EXAMINER		
				EPPS -SMITH, JANET L		
		ART UNIT	PAPER NUMBER			
		1633				
NOTIFICATION DATE		DELIVERY MODE				
08/21/2009		ELECTRONIC				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,655	<b>Applicant(s)</b> MACHIDA ET AL.
	<b>Examiner</b> Janet L. Epps-Smith	<b>Art Unit</b> 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on **5-06-09**.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) **1,3-6,12 and 14-31** is/are pending in the application.

4a) Of the above claim(s) **3,6-16 and 24-31** is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) **1,4,5,18 and 20-23** is/are rejected.

7) Claim(s) **17 and 19** is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3-6, 12, and 14-31 are pending.

***Election/Restrictions***

3. Claims 3, and 6-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
4. Newly submitted claims 24-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants are reminded that in the reply filed 07-07-2008, Applicants elected invention Group I, claims 1-2 and 4-5, drawn to DNA encoding a protein having 16-position hydroxylating enzymatic activity, partly or entirely or its variant. In addition, in the reply filed 10-22-08 Applicants elected variant A-I, drawn to a continuous nucleotide sequence from base 1322 to base 2548 of SEQ ID NO: 1.
5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-31 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
6. Claims 1, 4-5 and 17-23 are presently under examination.

***Claim Rejections - 35 USC § 112***

7. Claims 1 and 4-5 remain rejected and claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

8. Applicant's arguments filed 05-06-2009 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the description of the claimed invention, particularly at page 52, paragraph 1, page 68, paragraph 2, and page 77, paragraph 3 in the originally filed application, provides evidence that claimed sequences belong to a well-known family of nucleic acids encoding polypeptides, which were understood to contain conserved amino acid residues that correlate with the described enzymatic activity.

9. Applicants asserted that, at page 52, ¶ 1, it states that psmA has 72% homology with cytochrome P450 (CYP105D5), and 69.4% homology to cytochrome p450 soy. Based upon this homology Applicants concluded that the newly isolated gene of SEQ ID NO: 1, was "highly possibly a gene coding a hydroxylating enzyme of the cytochrome p450 type." Applicants further concluded at the bridging ¶ of pages 8-9 that due to the 64.8% homology shared between SEQ IDNO: 2 and cytochrome p450 soy, that "[I]t was considered from this fact that the bpmA highly possibly encoded hydroxylating enzyme of the cytochrome P-450 type." Additionally, Applicants stated that the homology shared

between the tpmA ORF of the polypeptides of the instant invention, suggested that "the tpmA was *highly possibly* a gene encoding hydroxylating enzyme of the cytochrome P-450 type."

10. Applicants further argued that the sequences described in part of claim 1 share approximately 70% to 80% identity with each other and share the described hydroxylating enzymatic activity.

11. In response to Applicant's assertions, Applicants have not provided any alignment or disclosure in the specification as originally filed that would support their assertion that the sequences disclosed in the instant specification are "approximately 70 to 80% identical," and further have not clearly set forth that the regions corresponding to the PsmA, BpmA and TpmA ORFs are responsible for the macrolide hydroxylating activity associated with the polypeptides encoded by the sequences of the instant invention. Applicants have merely demonstrated a high degree with a family of cytochrome p450 enzymes. Although Applicants have provided references which show common patches of residues conserved among various cytochrome p450 enzymes. Applicants have not provided a clear correlation between the presence of the PsmA, BpmA and TpmA conserved regions in the sequences of the instant invention and the macrolide hydroxylating activity of the sequences of the present invention. Therefore, contrary to Applicant's assertions, the ordinary skilled artisan would not know how to modify the sequences of the claimed invention in an effort to design sequences wherein 5%-10% of the sequence (which are 70-80% homologous, and therefore 20-30%

different) is modified and wherein the macrolide hydroxylating activity of the claimed sequences is conserved.

12. There is no clear guidance provided in the specification as filed, which would allow the skilled artisan to predict the structures of the full scope of DNA molecules encompassed by the instant claims.

13. See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

14. In the instant case it is concluded that there is not a sufficient amount of relevant identifying characteristics to describe the full scope of DNA molecules encompassed by the instant claims. Applicants have only provided guidance for the description of DNA molecules of SEQ ID NOs: 1-3, which possess the recited function of 11107B which encodes a protein having enzymatic activity in hydroxylating the 16-position of the macrolide compound. There is no guidance provided for varying the structures of these sequences in order to produce variants of these DNA molecules having the same functional characteristics of the DNA molecules of SEQ ID NO: 1-3.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claims 18 and 20 recite the limitation "amino acids 1-409 of SEQ ID NO: 1." This phrase is vague and indefinite since SEQ ID NO: 1 is defined as a DNA sequence, and not an amino acid sequence. In the sequence listing the field code <212> states that the sequence is drawn to a DNA sequence. Furthermore, Applicants have not provided a means for the Examiner to search amino acids 1-409 as encoded by SEQ ID NO: 1.

***Claim Rejections - 35 USC § 102***

18. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(b) as being anticipated by Nakajima et al. (WO03/040370 A1; Japanese; citations given from English equivalent document US 2005/0084859 A1), is withdrawn in response to Applicant's amendment.

***Claim Objections***

19. Claims 17 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633